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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,117	07/31/2003	Hilda Elizabeth Smith	2183-6055US	5350

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EXAMINER	
HINES, JANA A	
ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
06/20/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary	Application No.	Applicant(s)	
	10/632,117	SMITH, HILDA ELIZABETH	
	Examiner	Art Unit	
	JaNa Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,9 and 21-29* is/are pending in the application.

4a) Of the above claim(s) *1,6,9,28 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed April 2, 2008 has been entered. Claims 1, 9, and 21 have been amended. Claims 2-5, 8, 10-20 are cancelled. Claims 1, 6-7, 9 and 28-29 are withdrawn from consideration. Claims 28-29 are newly added. Claims 21-27 are under consideration in this office action.

Withdrawal of Objections and Rejections

2. The following objections and rejections have been withdrawn in view of applicants' amendments and arguments:

a) The objection of claim 21 because of the informalities;

b) The rejection of claims 11-15 under 35 U.S.C. 112, second paragraph;

c) The written description rejection of claims 11-15 under 35 U.S.C. 112, first paragraph;

d) The enablement rejection of claims 11-15 under 35 U.S.C. 112, first paragraph.

Response to Arguments

3. Applicant's arguments filed April 2, 2008 have been fully considered but they are not persuasive.

Response to Arguments

5. Applicant's arguments filed April 2, 2008 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The written description rejection of claims 21-27 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons already of record.

The claims are drawn to an isolated or recombinant nucleic acid molecule comprising a nucleotide sequence of *Streptococcus suis* origin wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 at 65°C in a buffer having 0.5 M sodium phosphate, 1 mM EDTA, and 7% sodium dodecyl sulphate at a pH of 7.2, wherein the nucleic acid molecule remains hybridized after washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 5% sodium dodecyl sulphate for 30 minutes at 65°C and; washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 1% sodium dodecyl sulphate for 30 minutes at 65°C and wherein the complement of the nucleotide sequence encodes for a fibronectin-/fibrinogen-binding protein of *Streptococcus suis.*

Applicants' argue that the structure of the isolated or recombinant nucleic acid molecules would be clear to one of ordinary skill in the art based on the description SEQ ID NO:37 because the gene encoding a fibronectin-/fibrinogen-binding protein of *Streptococcus suis* is by definition a double stranded nucleic acid molecule and inherently includes the full length of bases 89-263. The specification discloses the complete structure of only one species of the claimed genus of nucleic acids (i.e., SEQ ID NO:37). The specification does not indicate that any nucleic acids that both hybridize to SEQ ID NO:37 and the complement of the nucleotide sequence encodes for a fibronectin-/fibrinogen-binding protein of *Streptococcus suis* under the recited conditions. Thus applicants were not in possession of the isolated or recombinant nucleic acid molecule comprising a nucleotide sequence of *Streptococcus suis* origin wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 at 65°C in a buffer having 0.5 M sodium phosphate, 1 mM EDTA, and 7% sodium dodecyl sulphate at a pH of 7.2, wherein the nucleic acid molecule remains hybridized after washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 5% sodium dodecyl sulphate for 30 minutes at 65°C and; washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 1% sodium dodecyl sulphate for 30 minutes at 65°C and wherein the complement of the nucleotide sequence encodes for a fibronectin-/fibrinogen-binding protein of *Streptococcus suis.* Contrary to applicants assertions, possession of SEQ ID NO: 37 does not equate to possession of an isolated or recombinant nucleic acid molecule comprising a nucleotide

sequence of *Streptococcus suis* origin wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 and wherein the complement of the nucleotide sequence encodes for a fibronectin-/fibrinogen-binding protein of *Streptococcus suis.* Thus, Applicants arguments are not found persuasive.

Applicants urge that the recitation of the nucleotide sequence to hybridize to the full length of nucleotides 89-263 of SEQ ID NO:37 provides a common structure. However, because hybridization under highly stringent conditions requires a high degree of structural complementarity, nucleic acids that hybridize to SEQ ID NO::37 much share many nucleotides in common with SEQ ID NO:37. Thus the claimed genus necessarily includes partial structures of SEQ ID NO:37. The disclosure of SEQ ID NO:37 combined with the knowledge in the art regarding hybridization would put one in possession of the genus of nucleic acids that would hybridize under the recited conditions to SEQ ID NO:37. However, without a recognized correlation between structure and function, those of ordinary skill in the art would not be able to identify without further testing which of those nucleic acids that hybridize to SEQ ID NO:37 wherein the complement of the nucleotide sequence encodes for a fibronectin-/fibrinogen-binding protein of *Streptococcus suis* under the recited conditions. The scope of the claims includes numerous structural variants and the genus is highly variant because a significant number of structural differences between the genus members are permitted. The specification fails to provide guidance on the structure of the nucleic acid molecules. Thus, those of ordinary skill in art would not consider the

applicant to have been in possession of the claimed genus of nucleic acids based on the single species disclosed.

Therefore, applicants' arguments were not persuasive and the rejection is maintained.

Enablement Rejection

6. The enablement rejection of claims 21-27 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons already of record.

Applicants assert that amended claim 21 is enabled with respect to point (A), because the claim requires a region comprising a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of SEQ ID NO:37. However, the specification fails to provide an enabling disclosure specification for an isolated or recombinant nucleic acid molecule comprising a nucleotide sequence of *Streptococcus suis* origin wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 and wherein the complement of the nucleotide sequence encodes for a fibronectin-/fibrinogen-binding protein of *Streptococcus suis.*

There is no teaching of hybridization occurring at 65^{o}C in a buffer having 0.5M sodium phosphate, 1mM EDTA and 7% sodium dodecyl sulphate at a pH of 7.2. There is no teaching that the claimed nucleotide sequence wherein the nucleotide sequence

comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of SEQ ID NO:37 and wherein the complement of the nucleotide sequence encodes for a fibronectin-/fibrinogen-binding protein of *Streptococcus suis.* Therefore, the specification fails to enable an isolated or recombinant nucleic acid molecule of a *Streptococcus suis* origin as instantly claimed because the specification fails to teach the identity of such sequences. Such experimentation requires ingenuity beyond that expected of one of ordinary skill in the art. Such need for non-routine experimentation demonstrates that the specification is not enabled for any asserted use or well-established use of an isolated or recombinant nucleic acid molecule of a *Streptococcus suis* origin.

Thus, Applicants arguments are not found persuasive and the rejection is maintained.

New Grounds of Rejection Necessitated By Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 21-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for an isolated or recombinant nucleic acid molecule comprising a nucleotide sequence of *Streptococcus suis* origin wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 at 65°C in a buffer having 0.5 M sodium phosphate, 1 mM EDTA, and 7% sodium dodecyl sulphate at a pH of 7.2, wherein the nucleic acid molecule remains hybridized after washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 5% sodium dodecyl sulphate for 30 minutes at 65°C and; washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 1% sodium dodecyl sulphate for 30 minutes at 65°C and wherein the complement of the nucleotide sequence encodes for a fibronectin-/fibrinogen-binding protein of *Streptococcus suis.*

Applicant did not point to support in the specification for an isolated or recombinant nucleic acid molecule comprising wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 and wherein the complement of the nucleotide sequence encodes for a fibronectin-/fibrinogen-binding protein of *Streptococcus suis.* Moreover, applicant failed to specifically point to the identity or provide structural characteristics of the isolated or recombinant nucleic acid molecule. Thus, there appears to be no teaching of an isolated or recombinant nucleotide

sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 and wherein the complement of the nucleotide sequence encodes for a fibronectin-/fibrinogen-binding protein of *Streptococcus suis.* Applicant has pointed to paragraph [100] of the instant specification for support of the amendment, however paragraph [100] is drawn to a statement about the ethics committee's approval for the animal experiments. Furthermore, there is no teaching of the contiguous sequence which hybridizes to the full length of nucleotides 89-263. Thus, it appears that the entire specification appears to fail to recite support for the newly recited isolated or recombinant nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 and wherein the complement of the nucleotide sequence encodes for a fibronectin-/fibrinogen-binding protein of *Streptococcus suis.* Therefore, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line number support for the identity an isolated or recombinant nucleic acid molecule comprising wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 and wherein the complement of the nucleotide sequence encodes for a fibronectin-/fibrinogen-binding protein of *Streptococcus suis* as recited by the newly amended claim. Therefore, the claim incorporates new matter and is accordingly rejected.

Conclusion

8. No claims allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/
Examiner, Art Unit 1645

/Mark Navarro/
Primary Examiner, Art Unit 1645